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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,131

07/30/2003

George A. Lopez

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10/13/2006

EXAMINER

THANH, LOAN H

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,131

Applicant(s)

LOPEZ, GEORGE A.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 08/21/06, 1/17/06, 11/18/05, 8/29/05
- 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The 112 ,2nd paragraph rejection has been withdrawn in view of applicant's remarks filed 08/29/05.

The Application has no copies of the NPL listed in the IDS filed 07/30/03. Thus, applicant is requested to make these available if applicant intended for those references to be considered.

Information Disclosure Statement

The information disclosure statement filed 07/30/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of **each non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is requested to make these articles of record for the Examiner to consider.

The information disclosure statement (IDS) submitted on 08/21/06, 01/17/06, 11/18/05, 08/29/05 & 04/18/05 were filed after the first office action on the merits with the proper fee. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-34,38-41,44-45,48-56, 85-101, 103-105, 108-119 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt (USPN 4,998,927).

Vaillancourt discloses in figures 3-4 a valve device comprising a housing, with a first and second horizontal cross section wherein the second cross sectional width is larger than the first cross-sectional width, a flexible element disposed within the internal cavity of the housing having a first and second height wherein the first height is greater than the second height and a spike element 44. Further, Vaillancourt discloses a skirt and thread section in the distal portion of the housing.

Claims 25-119 are rejected under 35 U.S.C. 102(b) as being anticipated by Sunnanvåder (EP 0 309 771).

Sunnanvåder discloses a needleless valve comprising a housing having a first, second and third cross section, a flexible element 5 having an orifice and a spike 4. Further, a cap 24 is disclosed. See figures 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 35-37,42-43,46-48,57-84, 102,106-108 are rejected under 35 U.S.C.

103(a) as being unpatentable over Vaillancourt (USPN 4,998,927).

Vaillancourt discloses the invention as substantially claimed.

With respect to claims 35-37, Vaillancourt does not disclose a third cross section width. Lacking any criticality in the design choice of a third horizontal cross section width larger than the second cross sectional width, Examiner is taking the position that matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably distinguish the claimed invention from the prior art. The particular shape of a product is of no patentable significance since it appears to be a matter of choice that a person of ordinary skill in the art would find obvious absent persuasive evidence that the particular configuration of the claimed container was significant. In re Dailey, 357 F.2d 669,149 USPQ 47 (CCPA 1966).

With respect to claims 42-43, 57-84, 102, Vaillancourt is silent to the spike being formed of plastic. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the material of the spike to suit the area to which it would be applied to , since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended uses as a matter of obvious engineering choice lacking any criticality. In re Leshin , 125 USPQ 416.

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With respect to claims 46-47, 74-75, 106-107, Vaillancourt discloses the spike a certain distance from the proximal end of the housing. However, Vaillancourt is silent to the spike being positioned approximately 0.1" to 0.525" from the proximal end of the housing. Lacking any criticality in the specific range of the distance, the prior art would perform equally well since there is also a distance that the spike needs to be a distance from the proximal end of the housing in order to allow the valve to be activated upon application of a medical instrument to puncture and allow fluid flow therein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distance as determined by the length of the needle to pierce the septum in order to allow fluid to flow through the valve.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-119 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,682,509. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim an orifice. The patent claims recite a slit. Since a broad interpretation of a slit includes an orifice, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,682,509 patent.

Further, these other related patents are also cited for applicant to file a terminal disclaimer for the same/similar reasons as above.

US 6,669,673 – claims 1-7.

US 6,019,748 - claims 2-5.

US 5,685,866 – claims 1-17

US 5,700,248 – claims 1-3

US 5,738,663 – claims 1-4

US 6,132,404 – claims 1-3

US 6,325,782 – claims 1-3

US 6,572,592 – claims 1-30,35-38,43-44

US 6,758,833 – claims 1-10

Response to Arguments

Applicant's arguments filed 08/29/05 have been fully considered but they are not persuasive. With respect to applicant's arguments about the "generally flush" limitation, the examiner is interpreting this broadly and considers the prior art of Vaillancourt to anticipate the limitation. Applicant is arguing intended use with respect to the connector cannot be cleansed by a swab. Lacking any structurally distinguishing features, the Examiner is taking the position that the connector of the prior art can still be cleansed/swabbed. The rejection is maintained.

With respect to the arguments that there is no orifice in the septum of Vaillancourt, the Examiner is taking the position that an orifice is present during use as described by applicant.

With respect to the "no horizontal grooves" in the prior art, applicant is referred to figure 8 of Vaillancourt.

With respect to applicant's arguments to the limitations on page 18 of his argument, the examiner is not convinced. The rejection has been applied under a 103 rejection and is being maintained since size modifications are well known to one of ordinary skill in the medical arts.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 08/21/06, 01/17/06, 11/18/05, 08/29/05 & 04/18/05 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed; and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT